OIVD FY 2004 Premarket Customer Perception Survey Results

April 2005
Office of Management and Operations (OMO)
Division of Planning, Analysis, and Finance (DPAF)
Analysis Branch (AB)

Survey Background and Purpose

- Second Year of Survey
- Obtain industry feedback on the premarket review process to:
 - Help CDRH gauge how customers perceive the device review process.
 - Identify areas that may need improvement.
 - Use results in the 2005 Performance Scorecard Key Indicator "Knowledge Mgmt and Stakeholder Collaboration."

Methodology

- A random sample of industry contacts was selected from the FY 2004 premarket applications with final decisions.*
- Sample was proportionally allocated within each Office by application types.
- Respondents were contacted by telephone.
 (102 responses.)

OIVD Premarket Customer Perception Survey Demographics FY 2004 vs. FY 2003

Percent of Responses by Document Type:

	F 1 04	F 1 U 3
510(k)	79%	(85%)
PMA (Original)	2%	(0%)
PMA Panel Track	0%	(1%)
PMA Expedited	0%	(0%)
HDE		(0%)
Pre-IDE	20%	(14%)
IDE	1%	(0%)

Percent of Responses by Days to Decision:

	FY04	FY03
0-30 days	17%	(19%)
31-60 days	26%	(27%)
61-90 days	23%	(27%
91-180 days	23%	(21%)
181-365 days	12%	(6%)
366-above	0%	(1%)

Percent of Responses by Division:

	FY04	FY03
DCTD	35%	(34%)
DMD	28%	(35%)
DIHD	36%	(32%)

Percent of Responses by Decision Codes:

	FY04	FY03
SE or Approved	36%	(49%)
NSE or Not Approved	3%	(2%)
Withdrawn	0%	(2%)
Other	61%	(48%)

OIVD Premarket Customer Perception Survey FY 2004 vs. FY 2003

		Strong, Disagra		Disagre		A 91.00		S. A.			AIR
		FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03
No. of the	CDRH reviewed and processed your pre-market submission in a timely manner. (N=102 (107))	2%	(5%)	5%	(4%)	44%	(38%)	48%	(50%)	1%	(3%)
	 CDRH staff treated you in a fair, courteous, and professional manner. (N=102 (107)) 	0%	(0%)	1%	(2%)	19%	(20%)	79%	(79%)	1%	(0%)
Second Contract	3. CDRH review staff exhibited a level of scientific expertise appropriate to review your submission. (N=102 (107))	0%	(1%)	5%	(3%)	34%	(35%)	60%	(61%)	1%	(1%)
	 CDRH review staff applied consistent review procedures in processing your submission. (N=102 (107)) 	3%	(3%)	6%	(5%)	47%	(46%)	38%	(40%)	6%	(7%)
The sales	5. CDRH website information and guidance documents provided adequate direction on the format and recommended contents of your submission. (N=102 (107))	4%	(2%)	10%	(11%)	43%	(45%)	24%	(32%)	20%	(10%)

OIVD Premarket Customer Perception Survey FY 2004 vs. FY 2003

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	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03
 CDRH guidelines, standards, and policies are adequate to prepare your submissions on the latest advancement in technologies. (N=100 (106)) 	3%	(3%)	27%	(15%)	50%	(54%)	14%	(18%)	6%	(10%)
7. CDRH demonstrates that it uses the "least burdensome" approach in applying the regulatory process. (N=100 (105))	3%	(3%)	15%	(22%)	65%	(50%)	13%	(21%)	4%	(5%)
8. CDRH pre-market review meetings have been productive and have met your needs. (N=101 (106))	1%	(1%)	3%	(4%)	28%	(24%)	25%	(25%)	44%	(46%)
9. Overall, CDRH is customer service oriented. (N=102 (107))	0%	(4%)	10%	(7%)	57%	(49%)	33%	(40%)	0%	(0%)

Premarket Customer Perception Survey FY 2004 vs. FY 2003 DCTD

Strongly Disagree

Disagree

49ree

Strongly Agree of

AIR

	FY04 FY0	3 FY04 FY03	FY04 FY03	FY04 FY03	FY04 FY03
CDRH reviewed and processed your pre-market submission in a timely manner. (N=36 (36))	6% (3%	3% (6%)	42% (39%)	47% (53%)	3% (0%)
CDRH staff treated you in a fair, courteous, and professional manner. (N=36 (36))	0% (0%) 0% (3%	25% (17%)	75% (81%)	0% (0%
 CDRH review staff exhibited a level of scientific expertise appropriate to review your submission. (N=36 (36)) 	0% (0%	0% (0%)	36% (39%)	64% (61%)	0% (0%)
4. CDRH review staff applied consistent review procedures in processing your submission. (N=36 (36))	3% (3%) 3% (8%)	42% (36%)	44% (47%)	8% (6%)
5. CDRH website information and guidance documents provided adequate direction on the format and recommended contents of your submission. (N=36 (36))	8% (3%)	6% (8%)	53% (44%)	14% (33%)	19% (11%)

Premarket Customer Perception Survey FY 2004 vs. FY 2003 DCTD

	Strong Disagra		Disagree		49.0		Strong, Agree			AIR
	FY04 F	Y03	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03
6. CDRH guidelines, standards, and policies are adequate to prepare your submissions on the latest advancement in technologies. (N=36 (35))	3% (3	(%)	25%	(9%)	61%	60%)	11%	(17%)	0%	(11%)
7. CDRH demonstrates that it uses the "least burdensome" approach in applying the regulatory process. (N=35 (36))	0% (3	5%)	20%	(17%)	66%	(44%)	11%	(28%)	3%	(8%)
8. CDRH pre-market review meetings have been productive and have met your needs. (N=36 (35))	0% (3	3%)	3%	(3%)	25%	(23%)	22%	(14%)	50%	(57%)
9. Overall, CDRH is customer service oriented. (N=36 (36))	0% (3	3%)	8%	(11%)	50%	(44%)	42%	(42%)	0%	(0%)

Premarket Customer Perception Survey FY 2004 vs. FY 2003 DMD

Strongly Disagree

oisagree

49ree

Strongly Agree of

MA

	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03
CDRH reviewed and processed your pre-market submission in a timely manner. (N=29 (37))	0%	(5%)	3%	(3%)	52%	(35%)	45%	(49)	0%	(8%)
CDRH staff treated you in a fair, courteous, and professional manner. (N=29 (37))	0%	(0%)	0%	(0%)	17%	(24%)	83%	(76%)	0%	(0%)
 CDRH review staff exhibited a level of scientific expertise appropriate to review your submission. (N=29 (37)) 	0%	(3%)	10%	(5%)	38%	(24%)	52%	(65%)	0%	(3%)
CDRH review staff applied consistent review procedures in processing your submission. (N=29 (37))	3%	(5%)	10%	3%	45%	(57%)	38%	(24%)	3%	(11%)
5. CDRH website information and guidance documents provided adequate direction on the format and recommended contents of your submission. (N=29 (37))	0%	(3%)	10%	(14%)	34%	(51%)	31%	(24%)	24%	(8%)

Premarket Customer Perception Survey FY 2004 vs. FY 2003 DMD

	Strong! Disagra	Disagrae	49168	Stongly Agree	FILE
	FY04 FY03	FY04 FY03	FY04 FY03	FY04 FY03	FY04 FY03
6. CDRH guidelines, standards, and policies are adequate to prepare your submissions on the latest advancement in technologies. (N=28 (37))	4% (3%)	14% (22%)	54% (51%)	11% (16%)	18% (8%)
7. CDRH demonstrates that it uses the "least burdensome" approach in applying the regulatory process. (N=29 (36))	3% (6%)	7% (22%)	66% (47%)	14% (19%)	10% (6%)
8. CDRH pre-market review meetings have been productive and have met your needs. (N=29 (37))	3% (0%)	3% (5%)	38% (19%)	28% (38%)	28% (38%)
9. Overall, CDRH is customer service oriented. (N=29 (37))	0% (5%)	10% (3%)	62% (62%)	28% (30%)	0% (0%)

Premarket Customer Perception Survey FY 2004 vs. FY 2003 DIHD

Strongly Disagree

Oisagree

49ree

Strongly Agree of

AIR

	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03
CDRH reviewed and processed your pre-market submission in a timely manner. (N=37 (34))	0%	(6%)	8%	(3%)	41%	(41%)	51%	(50%)	0%	(0%)
2. CDRH staff treated you in a fair, courteous, and professional manner. (N=37 (34))	0%	(0%)	3%	(3%)	14%	(18%)	81%	(79%)	3%	(0%)
3. CDRH review staff exhibited a level of scientific expertise appropriate to review your submission. (N=37 (34))	0%	(0%)	5%	(3%)	30%	(41%)	62%	(56%)	3%	(0%)
CDRH review staff applied consistent review procedures in processing your submission. (N=37 (34))	3%	(0%)	5%	(3%)	54%	(44%)	32%	(50%)	5%	(3%)
5. CDRH website information and guidance documents provided adequate direction on the format and recommended contents of your submission. (N=37 (34))	3%	(0%)	14%	(12%)	41%	(38%)	27%	(38%)	16%	(12%)

Premarket Customer Perception Survey FY 2004 vs. FY 2003 DIHD

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	Strong		Ď,	Disagrae		40°		Agr. 60,01		AIR
	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03	FY04	FY03
6. CDRH guidelines, standards, and policies are adequate to prepare your submissions on the latest advancement in technologies. (N=36 (34))	3%	(3%)	39%	(15%)	36%	(50%)	19%	(21%)	3%	(12%)
7. CDRH demonstrates that it uses the "least burdensome" approach in applying the regulatory process. (N=36 (33))	6%	(0%)	17%	(27%)	64%	(58%)	14%	(15%)	0%	(0%)
8. CDRH pre-market review meetings have been productive and have met your needs. (N=36 (34))	0%	(0%)	3%	(3%)	22%	(29%)	25%	(24%)	50%	(44%)
9. Overall, CDRH is customer service oriented. (N=37 (34))	0%	(3%)	11%	(9%)	59%	(38%)	30%	(50%)	0%	(0%)

Comments or Suggestions on CDRH's premarket review process...

Top Nine Responses for OIVD out of 114 Responses

- 26% pleased with process
- 18% none
- 14% lack of consistency
- 14% problems with communication
- 10% guidance documents need updating
- 8% website needs improving
- 4% FDA is not least burdensome in approach
- 4% user fees excessive
- 4% reviews not timely



Types of Comments Included in each of the most frequent responses:

Pleased with process 26%

- Very supportive and helpful, things are going smoothly
- I am pretty happy with our submissions. The questions have been appropriate and well formulated to our submissions
- 510(k) process has been good. Review times are getting shorter for us.

None 18%

lack of consistency 14%

- Review process differs from product to product, not consistent
- Review process is handled differently between the microbiology and
- immunology branches
- Inconsistent from division to division

Problems with communication 14%

- We would like more dialogue with reviewers before application submission
- If reviewer has questions, they should not delay talking to sponsor
- Internal policies change and we are not informed



Types of Comments Included in each of the most frequent responses: (continued)

Guidance documents needs updating 10%

- Current guidance documents need to be updated annually
- No guidance documents in technical area
- Need more device specific guidance documents
- Guidance are behind new technologies

Website needs improving 8%

- The website is impossible to follow and is not user friendly
- Website does not have all of the information needed
- The website needs to be simplified its too difficult to find items



Types of Comments Included in each of the most frequent responses: (continued)

Fees are excessive or shouldn't exist 4%

- Fees increased too much
- Expensive for small companies
- Remove user fees

Not timely reviews 4%

- IDEs should go faster
- Our 510(k) special took longer than a traditional
- Request for additional info causes restart of 90-day clock and is not efficient

"Least Burdensome" concerns 4%

- Too much time spent on things not relevant
- Encourage more of the "least burdensome" approach

